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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,870	06/02/2004	Mitchell I. Kirschner	P017US-P2	3869

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KV PHARMACEUTICAL COMPANY
4080B WEDGEWAY COURT
EARTH CITY, MO 63045

EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
04/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/709,870	KIRSCHNER ET AL.	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) *30-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060324,20060921*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Invention I, claims 1-29 in the reply filed on 1/28/2008 is acknowledged. The traversal is on the ground(s) that the point of novelty is common to all pending claims. This is not found persuasive because the Applicant fails to identify the point of novelty. In any case, the mere fact that the claims have common elements is not sufficient to traverse the restriction requirement. If the inventions did not have common elements they would not be related inventions. Related inventions, however, may still be subject to restriction. Since the Applicant has not provided a valid reason to overcome the restriction, the restriction is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 30-88 are withdrawn as directed to a non-elected invention. Claims 1-29 are product claims, as such, the Examiner reminds the Applicant that the non-elected process claims are subject to rejoinder. See Office Action (1/20/2008), pgs 4, 5.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 10, 11, 17,18, 24, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Borkan et al. (US Pat. 4,935,243).

Borkan et al. expressly discloses a soft gelatin capsule containing ascorbic acid, iron, sodium saccharin, orange flavoring, citric acid and vegetable oil (Column 6, lines 55-68, Example 1).

It is inherent that the vegetable oil will contain linoleic acid. See Prasad et al. (1992).

Claims 1-7, 10-13, 11, 17,18, 24, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Borkan et al. (US Pat. 4,935,243) in view of Prasad et al.

Borkan et al. discloses a soft gelatin capsule containing ascorbic acid, iron, sodium saccharin, orange flavoring, citric acid and vegetable oil (Column 6, lines 55-68, Example 1). It is disclosed that the vegetable oil can include corn oil, peanut oil, safflower oil, sunflower oil and soybean oil (Column 5, lines 50-55).

Prasad et al. (1992) discloses that groundnut oil, sunflower oil, soyabean oil, mustard oil, till oil, maize oil and palm oil contain the n-6 fatty acid, linoleic acid, and that mustard, soyabean, palm and maize oils also contain the n-3 fatty acid, alpha-linolenic acid (Pages 200-202).

The prior art discloses a soft gelatin capsule containing ascorbic acid, iron, sodium saccharin, orange flavoring, citric acid and vegetable oil. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the presence of essential oils. However, the prior art amply suggests the same as the prior art discloses that use of vegetable oils, such as corn oil, peanut oil, safflower oil, sunflower oil and soybean oil, as

vehicles, and that vegetable oils contain omega-6 fatty acids or omega-6 fatty acids and omega-3 fatty acids. As such, one of ordinary skill in the art would expect that the vegetable oil would be a suitable vehicle for use in soft gelatin capsules and that addition of the same would result in the soft gelatin capsule containing essential fatty acids.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yehuda (US Pat. 4,851,431) in view of the acknowledged prior art, Chang et al. (US Pat. 4,874,629), Markham (US Pat. 4,968,716), The Merck Index , GB1342974 and Gordeuk et al..

Yehuda discloses a composition that can be in the form of gelatin capsules and containing linoleic and linolenic acid, pyridoxine, folic acid, ascorbic acid, calciferol, tocopherol, calcium, iron, arachidonic acid and eicosapentaenoic acid (Columns 3-4, Column 5, lines 1-20).

The Applicant acknowledges that arachadoinc acid, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are essential fatty acids, that EPA and DHA are omega-3 fatty acids, that linoleic acid is an important precursor of the omega-6 family of acids and that linolenic acid is an important precursor of the omega-3 family of fatty acids (Specification, paragraphs 0003-0006).

Chang et al. disclose that eicosapentaenoic acid is an omega-3 fatty acid and that fish oils are a source of omega-3 fatty acids which also include docosahexenoic acid and have high pharmacological and dietary potential (Column 1, lines 20-43). It is disclosed that the stability of fish oils can be further increased by mixing with antioxidants and/or vegetable oils, such as

sunflower oil (Column 6, lines 1-13). It is disclosed that fish oils can be contained in soft gelatin capsules (Column 5, line 61).

Markham discloses that the combination of calcium ascorbate with edible salts of L-threonic acid improves the establish and maintenance of high levels of vitamin C in the human body (Column 2, lines 50-68, Column 3, lines 1-28).

The Merck Index discloses that calcium phosphate, tribasic is used therapeutically as a calcium replenisher and that vitamin D3 is bioequivalent to vitamin D2(calciferol) in humans (Pages 256, 1578, 1579).

GB1342974 discloses an edible preparation containing lipoid material subject to rancidity and an enriching nutritionally available iron source in particulate form, in which the iron-containing particles are encapsulated to overcome the effect of iron on the lipoid material (Claim 1).

Gordeuk et al. disclose that carbonyl iron is a safe, effective, well-tolerated and inexpensive therapy for iron deficiency anemia and can decrease accidental iron poisoning in children which has been seen with the use of ferrous salts (Page 751).

The prior art discloses a composition that can be in the form of gelatin capsules and containing linoleic and linolenic acid, pyridoxine, folic acid, ascorbic acid, calciferol, tocopherol, calcium, iron, arachidonic acid and eicosapentaenoic acid (Columns 3-4, Column 5, lines 1-20). The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of a soft gelatin capsule, the use of sunflower oil, the use of calcium ascorbate and calcium threonate as a source of Vitamin C, the use of vitamin D3, the use of calcium phosphate, tribasic, and the use of encapsulated iron or carbonyl iron as the source of

iron. However, the prior art amply suggests the same as the prior art discloses and/or suggests that fish oils can be contained in soft gelatin capsules, that sunflower oil stabilizes fish oils, the combination of calcium ascorbate and calcium threonate increases the bioavailability of Vitamin C, that vitamin D3 is bioequivalent to calciferol in humans, that calcium phosphate, tribasic is a source of calcium, that encapsulated iron inhibits rancidity of oils caused by the interaction of iron with said oils and that carbonyl iron is a safe and effective nutritional supplement. As such, one of ordinary skill in the art would have been motivated to modify and/or combine the prior art with the expectation that soft gelatin capsules would be a suitable dosage form for nutritional compositions containing oils and essential fatty acids and that the use of sunflower oil would be effective in stabilizing fish oils which are a source of omega-3 fatty acids and that in the nutritional compositions that calcium ascorbate and calcium threonate would be a suitable source of vitamin C, that vitamin D3 would be a suitable substitute for calciferol, that calcium phosphate, tribasic would be a suitable source of calcium and that encapsulated iron or carbonyl iron would be a suitable source of iron.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. US Pat 6,258,846 in view of Yehuda (US Pat. 4,851,431), Chang et al. (US Pat. 4,874,629), Markham (US Pat. 4,968,716), The Merck Index, GB1342974 and Gordeuk et al..

The claims of said US Patent disclose a composition containing a mixture of linoleic and/or linolenic acids and docosahexaenoic acid, omega-3 fatty acid, and/or omega-2 fatty acid to which can be combined a B complex vitamin, vitamin C compound, vitamin D compound, Vitamin E compound, calcium and/or iron, where the composition can be in the form of a soft gelatin capsule (claims 1-22).

Yehuda (US Pat. 4,851,431), Chang et al. (US Pat. 4,874,629), Markham (US Pat. 4,968,716), The Merck Index, GB1342974 and Gordeuk et al. are cited here for the same reasons as above.

The claims of said US Patent disclose a soft gelatin capsule containing a mixture essential fatty acids and iron and other vitamins and minerals as indicated above. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of sunflower oil, the use of vitamin B6, the use of calcium phosphate, tribasic, the use of folic acid,

the use of calcium ascorbate and calcium threonate as a source of Vitamin C, the use of vitamin D3 and the use of encapsulated iron or carbonyl iron as the source of iron. However, the prior art amply suggests the same as the prior art discloses and/or suggests the use of pyridoxine and folic acid in nutritional supplements, that sunflower oil stabilizes fish oils, the combination of calcium ascorbate and calcium threonate increases the bioavailability of Vitamin C, that calciferol can be combined with essential fatty acids and that vitamin D3 is bioequivalent to calciferol in humans, that calcium phosphate, tribasic is a source of calcium, that encapsulated iron inhibits rancidity of oils caused by the interaction of iron with said oils and that carbonyl iron is a safe and effective nutritional supplement. As such, one of ordinary skill in the art would have been motivated to modify and/or combine the prior art with the expectation that the use of sunflower oil would be effective in stabilizing fish oils which are a source of omega-3 fatty acids, that pyridoxine would be a suitable source of vitamin B, that folic acid can be combined with essential fatty acids in a nutrition supplement and that in the nutritional compositions that calcium ascorbate and calcium threonate would be a suitable source of vitamin C, that vitamin D3 would be a suitable substitute for calciferol, that calcium phosphate, tribasic would be a suitable source of calcium and that encapsulated iron or carbonyl iron would be a suitable source of iron.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of said US Patent to one ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of said claims and the references.

Claims 1-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. US Pat 7,112,609 or claims 1-23 of US Pat. 6,576,666, each in view of Yehuda (US Pat. 4,851,431), Chang et al. (US Pat. 4,874,629), Markham (US Pat. 4,968,716), The Merck Index, GB1342974 and Gordeuk et al..

The claims of said US Patents disclose a composition containing a mixture of linoleic, linoleic acid, docosahexaenoic, eicosapentaenoic, omega-3 fatty acid, and/or omega-2 fatty acid, vitamin B6, folic acid, calcium, vitamin C, vitamin E to which can be add iron, wherein the composition can be in the form of a soft gelatin capsule (claims 1-8 of the '609 patent; claims 1-23 of the '666 patent).

Yehuda (US Pat. 4,851,431), Chang et al. (US Pat. 4,874,629), Markham (US Pat. 4,968,716), The Merck Index, GB1342974 and Gordeuk et al. are cited here for the same reasons as above.

The claims of said US Patent disclose a soft gelatin capsule containing a mixture essential fatty acids and iron and other vitamins and minerals as indicated above. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of sunflower oil, the use of calcium ascorbate and calcium threonate as a source of Vitamin C, the use of calcium phosphate, tribasic, the use of vitamin D3 and the use of encapsulated iron or carbonyl iron as the source of iron. However, the prior art amply suggests the same as the prior art discloses and/or suggests the use that sunflower oil stabilizes fish oils, the combination of calcium ascorbate and calcium threonate increases the bioavailability of Vitamin C, that calciferol can be combined with essential fatty acids and that vitamin D3 is bioequivalent to calciferol in humans, that calcium phosphate, tribasic is a source of calcium, that encapsulated

iron inhibits rancidity of oils caused by the interaction of iron with said oils and that carbonyl iron is a safe and effective nutritional supplement. As such, one of ordinary skill in the art would have been motivated to modify and/or combine the prior art with the expectation that that the use of sunflower oil would be effective in stabilizing fish oils which are a source of omega-3 fatty acids and that in the nutritional compositions that calcium ascorbate and calcium threonate would be a suitable source of vitamin C, that vitamin D3 would be a suitable substitute for calciferol, that calcium phosphate, tribasic would be a suitable source of calcium and that encapsulated iron or carbonyl iron would be a suitable source of iron.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of said US Patent to one ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of said claims and the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
Monday, April 21, 2008

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616